

## REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 29-48) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides hygienic protection for endoscopes, so that such instruments, which have become highly valuable medical diagnostic and procedure tools, can be readily re-used on a patient following recent use on a prior patient. Endoscopes, lacking proper protection against contamination, must generally be dismantled after each use and thoroughly cleaned, which is both time-consuming and quite expensive.

The present invention, as now claimed, provides hygienic protection for an endoscope, which includes a cover, which is closed at its distal end and which is transparent for optical information, at least on the front side thereof, with the cover able to be rolled thereon in a direction of the axis of the endoscope. One or more working channels for the endoscope extend in a parallel position in relation to the endoscope and terminate in an open manner on the distal end of the cover – the working channel being connected only to the distal end of the cover. The working channels are positioned between the outside of the endoscope and the inner side of the cover. There are one or more vacuum channels, having one or more openings, which terminate at the inside of the cover on the side facing away from the patient, which are in addition to the working channels. As now explicitly claimed, the working channel(s) and the vacuum channel(s) are entirely

separate from one another, in that the one or more working channels are not useful for use as a vacuum channel, and vice versa, in contrast to the applied prior art.

More particularly, the vacuum channels terminate in an open manner within the envelope of the endoscope protection and can have additional side openings. These side openings advantageously terminate at the inside of the cover on the side of the cover (*i.e.*, an inner side or inner surface of the cover) facing away from the patient. When a vacuum is applied to this channel, the air located between the cover and endoscope shaft is sucked out with the consequence being that the cover is drawn firmly onto the endoscope. The vacuum is then maintained during the examination. Thus, a fixed connection between the cover and endoscope, is produced advantageously and rapidly after the endoscope has been introduced into the cover, which is dimensioned somewhat larger in the interior diameter, preferably in the proximal part.

During application of the hygiene protection, one hand of the medical practitioner fixes the freely movable working channels and vacuum channels on the endoscope shaft, while the practitioner's other hand rolls on the cover above the channels. The combination of a protective cover, with its own working channels, extends outside of the endoscope with the protective cover and the working channels being connected to one another in the distal region of the cover in an airtight and germ-free manner. For attachment of the protection cover in accordance with the presently-claimed invention, the distal end of the cover is pushed onto the endoscope, so that the front face, which is transmissible for optical information, is correctly positioned, *i.e.*, positioned parallel to the distal end of the

endoscope. The optical contact between the endoscope and the transparent front face of the cover is preferably produced by means of a fluid, such as microscope immersion oil, which ideally has the same refractive index as the lens of the endoscope.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and vacuum channels, in which the openings of the vacuum channels terminate at the inside of the cover of the endoscope protection at an inner side of the cover facing away from the patient, either disclosed or suggested.

By the present amendments, Applicant has amended independent Claims 29, 47 and 48 to now recite that the “vacuum channel [is] a channel that is a different channel from said working channel” to clarify, and distinctly recite, that a single channel cannot be used as both a “working channel” and a “vacuum channel,” which is submitted to render the present invention, as now claimed, distinguishable over Adair, U.S. Patent No. 5,630,782, as discussed in greater detail hereinafter.

Non-substantively, the claims have been amended to now recite “a working channel” and “a vacuum channel,” as opposed to “at least one working channel” and “at least one vacuum channel.” No change in the scope of the claimed invention is intended by this amendment, which is being entered solely for the purpose of clarity. The use the transitional claim term “comprising” inherently means that “a” working channel or “a” vacuum channel includes the plural of these claim elements. The purpose for this amend-

ment, which included the amendment of several dependent claims for the purpose of deleting “at least one,” is to avoid otherwise grammatically clumsy or confusing claim language without any meaningful benefit or increase claim scope.

Finally, independent Claims 29, 47 and 48 have been amended to further clarify that it is “an inner side of said cover” that “faces away from a patient.” The purpose of this amendment is to address the Examiner’s 35 U.S.C. §112, second paragraph, indefiniteness rejection of Claims 29-48 of the latest Office Action, in which the Examiner stated that, since the cover is entirely “surrounded” by a patient when in use, it is unclear what “side” would be facing away from a patient. By explicitly reciting that “an inner side” of the cover faces away from the patient, the location of the endoscope, when in use, relative to the patient does not undermine the point of reference made to the “patient.”

As part of the indefiniteness rejection of the final Office Action, the Examiner also objected to the use of the “patient” as a reference in Applicant’s claims, contending that a “patient,” or presumably any “person,” cannot be part of a claim. The Examiner’s position, as best understood by Applicant’s counsel, is correct, as a general proposition, but misapplied in this instance to the present Applicant’s claims: While a human being can neither be “claimed” as an “invention,” nor be an “element” of any claimed invention, there is no prohibition against reciting a “person,” *per se*, in a claim as a point of reference. In this respect, as examples, the Examiner is referred to the following patents which make reference to a person as part of claiming the invention disclosed therein:

1. Jannard *et al.*, U.S. Patent No. 6,325,507, issued December 4, 2001, discloses an "eyewear retention system extending across the top of a wearer's head."

2. Binder *et al.*, U.S. Patent No. 7,297,128, issued November 20, 2007, which discloses an "arm suspension sleeve," and, which the Abstract of this patent explains, provides "more comfortable gel treatment to the skin."

A wide-range of inventions are used by humans and the patents disclosing these types of inventions invariably recite humans as reference points for whom such inventions are so intended.

In view of the foregoing, it is respectfully contended that independent Claims 29, 47 and 48, as now amended, are sufficiently definite in reciting the claimed subject matter. Accordingly, withdrawal of the Examiner's 35 U.S.C. §112, second paragraph, indefiniteness rejection is respectfully requested.

Accompanying the present *Amendment in Response to the Final Office Action*, Applicant is filing a *Request for Continued Examination* and formal *Petition for a Three-Month Extension of Time* for response, and remitting all required fees. Accordingly, the "finality" of the last Office Action should be withdrawn and the foregoing amendments presented herein entered, and considered on their merits, as a matter of right.

Turning now, in detail, to an analysis of the Examiner's prior art rejection, in the latest Office Action the Examiner has rejected independent Claims 29, 47 and 48 as being obvious, pursuant to 35 U.S.C. §103(a), over Silverstein *et al.*, U.S. Patent No. 5,646,722,

taken in view of Adair, U.S. Patent No. 5,630,782 (“Adair ‘782.”) It is the Examiner’s contention that Silverstein *et al.* discloses an endoscope having a cover, but fails to disclose a vacuum channel having at least one opening and terminating at a side of said cover facing away from the patient, as well as failing to disclose a working channel detachably connected to the distal end of the cover. The Examiner has therefore secondarily-applied Adair ‘782 for its contended teaching of a cover used to protect the insertion portion of an endoscope having channels (22, 24) which terminate at a side of the cover facing away from a patient and which channels are contended to be in communication with vacuum or fluid sources. The Examiner has, therefore, concluded that it would have been obvious to have provided the endoscope protection/cover of Silverstein *et al.* with the structure of the channels (22, 24) disclosed by Adair ‘782, detachably connected to the distal end of the protective cover of Silverstein *et al.*, to arrive at that which is claimed by the instant Applicant.

In reply to the Examiner’s obviousness rejection applying Silverstein *et al.*, taken in view of Adair ‘782, the primarily-applied citation of Silverstein *et al.* discloses an endoscope with a cover having a channel (36), which is apparently used for biopsy purposes. There would appear to be no vacuum channel taught or suggested by Silverstein *et al.*, and the Examiner and Applicant would appear to be in agreement on this point.

With respect to the secondarily-applied reference of Adair ‘782, this reference shows a sterilizable endoscope with working channels, as denoted by reference numerals

22 and 24. However, unlike that which is now claimed by Applicant, the referenced working channels, as taught by Adair '782, are to have a vacuum applied thereto, thereby using the same channel(s) as both a "working channel" and a "vacuum channel," unlike the present invention, as now claimed, in which the working channel(s) and vacuum channel(s) are distinctly different channels and, consequently, combining the teachings and suggestions of Silverstein *et al.*, with those provided by Adair '782, would fail to yield that which is now claimed by Applicant.

It should further be pointed out that both Silverstein *et al.* and Adair '782 are similar in disclosure, however, in contrast to the presently claimed invention, each is unable to fix a protective endoscope cover by exerting a vacuum-based source between the cover and the outer surface of the endoscope.

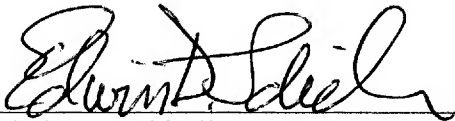
In light of the foregoing, it is respectfully submitted that the Examiner's 35 U.S.C. §103(a) obviousness rejection, which applies Silverstein *et al.*, taken in view of Adair '782, has been overcome and should now be withdrawn.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 29-48) recite a novel and hygienically effective protection apparatus and related method for an endoscope, wherein one or more separate working channels and vacuum channels are provided, in which the openings of the vacuum channels terminate at the inside of the cover of the endoscope protection at an inner side of the cover facing away from the patient, which is patentably

distinguishable over the prior art. Accordingly, withdrawal of the outstanding rejection and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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- Enc.: 1. Petition for Three-Month Extension of Time for Response;
2. *Request for Continued Examination*, pursuant to 37 C.F.R. §1.114; and,
3. EFT for \$930.00 (*Request for Continued Examination* filing fee + Three-Month Extension Fee);

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (Account No. 19-0450) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.